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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/932,141 | 08/17/2001 | Kari Parmer | 723.018US1 | 5151 |

21186 7590 12/02/2003

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| EXAMINER |
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ROBERT, EDUARDO C

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| ART UNIT | PAPER NUMBER |
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3732

DATE MAILED: 12/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/932,141

Applicant(s)

PARMER ET AL.

Examiner

Eduardo C. Robert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-35 is/are pending in the application.
- 4a) Of the above claim(s) 21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 22, 27, 28, 30 and 32-35 is/are rejected.
- 7) ☒ Claim(s) 16-20, 25, 26, 29 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Information Disclosure Statement

The information disclosure statement for the listed application 09/828,451, filed September 15, 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy for each cited pending U.S. application, the application specification including the claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 32, lines 5-6, applicants recite "expanding a material about the first passage to reduce an effective area of the material around the instrument to immobilize the instrument". This step appears to be new matter because the disclosure as originally filed does not disclose

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any “expanding” of a material about the first passage to “reduce an effective area of the material ... to immobilize the instrument. It is noted that in applicant’s specification page 17, lines 22, through page 18, line 11, the applicants explain how the relaxable stabilizer 227 works, e.g. a tool is used to increase the inside diameter of the opening 228 of the stabilizer 227, until the opening 228 is of a diameter large enough to accept the outer diameter of the stem guide 240, thus permitting the stem to be fully inserted into the opening 228, then an instrument 229 may be inserted into the guide 240, the guide 240 is removed and the relaxable stabilizer 227 will attempt to return to its original size thus applying pressure to the outer diameter of the instrument 229. In this disclosure there is no suggestion or indication of expanding a material to reduce an effective area of the material to immobilize an instrument.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 22, 27, 28, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Paleschuck (Reference U.S. Patent 3,402,710 cited in IDS by applicant).

Paleschuck discloses a method including the steps of providing a relaxable material 11, e.g. silicone, having a passage; introducing an instrument into the passage, e.g. a catheter; reducing an effective area of the material around the instrument by self-relaxing the material, e.g. the passage is clearly of a smaller diameter than the catheter so that when the catheter is inserted

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through the passage the passage will allow the catheter to go through however the relaxable material 11 will tempt to return to it original size thus applying pressure to the outer diameter of the catheter thus temporarily immobilizing the catheter and preventing any leakages. With regard to claim 28, Paleschuck also discloses the steps of aiming a first passage to align its axial trajectory with a target, e.g. implanting the device having the passage of the relaxable material 11 in direction to a target; locking the first passage in an aligned position, e.g. implanting the device. Also, it is noted that the step of expanding the material, recited in claim 32, is considered to be the tendency of the silicone to return to it original configuration, i.e. expanding toward the center of the passage thus fixing the catheter in place and preventing leakage.

Claims 28, 30, 32, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte (Reference U.S. Patent 3,444,861 cited on IDS by applicant).

Schulte disclose a method including the steps of providing a relaxable material 22, e.g. silicone, having a passage; introducing an instrument into the passage, e.g. a tube 10; reducing an effective area of the material around the instrument by self-relaxing the material, e.g. the passage is clearly of a smaller diameter than the tube so that when the tube is inserted through the passage the passage will allow the tuber to go through however the relaxable material 22 will tempt to return to apply pressure to the outer diameter of the tube thus immobilizing the tube and preventing any leakages. With regard to claim 28, Schulte also discloses the steps of aiming a first passage to align its axial trajectory with a target, e.g. implanting the device having the passage of the relaxable material 22 in direction to a target; locking the first passage in an aligned position, e.g. implanting the device. Also, it is noted that the step of expanding the

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material, recited in claim 32, is considered to be the tendency of the silicone apply pressure to the outer diameter of the tube. Schulte also includes bending the tube.

Response to Arguments

Applicant's arguments with respect to claims have been considered but are moot in view of the new ground(s) of rejection.

Allowable Subject Matter

Claims 16-20, 25, 26, 29, and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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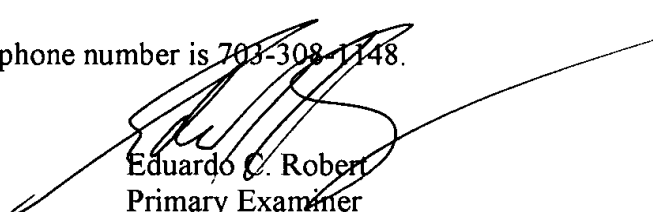
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eduardo C. Robert whose telephone number is 703-305-7333.

The examiner can normally be reached on Monday-Friday, 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P. Shaver can be reached on 703-308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.



Eduardo C. Robert
Primary Examiner
Art Unit 3732

E.C.R.